Remarks

Claims pending in this application are claims 1-18. Claim 18 is canceled without prejudice as pertaining to a non-elected invention. Claims 7, 9, and 10 are canceled as unnecessary in view of the amendments to claim 1. New claims 19 - 26 are added for which support is found through out the application. Upon entry of the foregoing amendments claims 1-17 and 19-26 will be before the Examiner for consideration.

At page 2, the Examiner objects to the declaration. A new declaration has been prepared and is being executed by the inventors. The new declaration will soon follow this response which will address the Examiner's concerns, i.e., specifying the citizenship of the inventors. Reconsideration is requested.

Claims 2, 9, and 10 stand rejected under 35 USC § 112, second paragraph. Claim 2 is rejected as it is said the term "SEB" is indefinite. Applicants respectfully traverse. The specification, at page 8, for example, fully describes SEB and cites to several patents which describe SEB in great detail. One skilled in the art would clearly understand that SEB is an acronym for Staphylococcal enterotoxin B. The rejection as it applies to claims 9 and 10 is obviated in view of the above claim amendments. Applicants respectfully request the reconsideration and withdrawal of this rejection under 35 USC § 112, second paragraph.

Claims 1-13 are rejected under 35 USC § 112, first paragraph. The Examiner states that the claims are enabled for a method of treating cancer but not for a method of preventing cancer. Applicants assert that the amendments to claim 1 obviate this rejection. Claim 1 has been amended to recite that the method induces a patient's immune responses in a specific way to enhance their resistance to the onset of cancer. Applicants believe that the rejection is perhaps based on the use of the term prophylaxis, or in other words claim the prevention of cancer. Applicants hold to their position that prevention of cancer can occur by effectuating the method as originally defined in claim 1. While prevention in all cases may be difficult to confirm, resistance to the onset of cancer is clearly taught and demonstrated in the specification. The Examiner, citing to

examples 1 and 2, states in the office action that the specification teaches methods that demonstrate a delay in the onset of disease and an increase in survival times. The value of such results is immeasurable, especially to a person who may be predisposed to developing a certain form of cancer, such as melanoma.

The Applicants have modified claim 1 above to address the Examiner's stated concern with respect to claiming a "prevention" to cancer. Accordingly, Applicants assert that claim 1 as amended is fully enabled, as well as all dependent claims flowing therefrom. Applicants respectfully request the reconsideration and withdrawal of the rejection under 35 USC § 112, first paragraph.

Next, claims 1-5, 7, 9, and 14-17 are rejected under 35 U.S.C. § 102(b), as being anticipated by Kominsky *et al.* Applicants traverse. The Kominsky *et al.* reference the Examiner cites to is not a valid prior art reference for this rejection. At the paragraph bridging pages 4 and 5, the Examiner correctly points out that the priority date of the subject application is April 1, 2000. Furthermore, the rejected claims are fully enabled by the disclosure in provisional application 60/194,951. Therefore, even assuming, *arguendo*, that the Kominsky et al reference was made available to the public before April 1, 2000, it is not a reference that was available more than a year before the priority of the subject application. Since the Kominsky et al reference cannot properly serve as the basis for this rejection, reconsideration and withdrawal of this 35 U.S.C. § 102(b) rejection is respectfully requested.

At page 6, the office action rejects claims 1-5, 7, 9 and 14-17 under 35 U.S.C. § 102(b), as being anticipated by WO 98/26747 ('747 publication). Applicants respectfully traverse. The first overriding focus of the '747 publication pertains to the in vitro expansion of a T-cell clonal population, involving the treatment of an antigen and superantigen. The T-cell population can then be later infused into a patient in need. Second, the '747 publication teaches a conjugate or polymer that involves the joining of a immunotherapeutic antigen with a superantigen.

Indeed, but for the glib and ambiguous statement at page 19 that the specific antigen and superantigen can be administered separately, there is simply no teaching in the '747 publication of a method where a specific antigen is administered to a patient (prior to and separate from a superantigen), followed by the administration of a superantigen at a later predetermined time and dosage. In fact, the only discussion regarding an *in vivo* vaccination scheme actually teaches away from the methods as claimed. At page 9 of the '747 publication, end of second paragraph, it states that "[I]n vivo anergy is induced by adminstration of superantigen parenterally or in the form of an adjuvant." This is further echoed at page 79, where the '747 publication teaches that "anergy may be produced by preimmunization with peptide in solution followed within 6-30 days by superantigen given parenterally." Page 79, end of first full paragraph. The production of anergy is directly counter to the purpose of the claimed methods. The claimed methods are intended to induce the immune response against a targeted antigen, not reduce it.

Accordingly, in view of the above reasoning, the '747 publication lacks the necessary teaching in order to be a valid anticipatory reference. Specifically, the skilled artisan, from following the teachings of the '747 publication, would not know to perform a method that involves *in vivo* administration of a specific antigen associated with an undesired pathological condition, such as a cancer associated antigen, followed by the *in vivo* administration of a superantigen. Indeed, the skilled artisan would strictly want to avoid such a method because, as the '747 publication teaches, may desensitize the patient immune response to the pathological condition. Therefore, the '747 publication does not teach all of the elements of the claims as required to be an anticipatory reference. Reconsideration and withdrawal of this 35 U.S.C. § 102(b) rejection is respectfully requested.

Lastly, claims 6 and 8 are rejected under 35 U.S.C. § 103(a), as being obvious over the Kominsky et al. reference. Applicants traverse, and reiterate the arguments provided above regarding the Kominsky et al. reference. As it is not an appropriate

reference under 35 U.S.C. § 102(b), it is also not a valid reference under 35 U.S.C. § 103. Accordingly, reconsideration of this rejection is respectfully requested.

Applicants assert that all claims are in a condition for allowance, and such action is respectfully requested. Applicants invite the Examiner to call the undersigned if clarification is needed on any aspect of this response after entrance and consideration of the remarks presented herein.

Respectfully submitted,

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